DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 9, 2015

Pac-Dent International, Inc.
Ms. Wenying Zhu
Materials Engineer
21038 Commerce Point Dr.
Walnut, California 91789

Re: K141717
Trade/Device Name: Pacseal Pit & Fissure Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and fissure sealant and conditioner
Regulatory Class: Class II
Product Code: EBC
Dated: January 29, 2015
Received: February 6, 2015

Dear Ms. Zhu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Section III

Indications for Use Statement

510(k) Number (if known): K141717

Device Name: PacSeal™ Pit & Fissure Sealant

Indications for Use:

PacSeal™ Pit & Fissure Sealant is intended for use as:

- Seal the pits and fissures in teeth

Prescription Use X OR Over-The-Counter Use _____

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Section IV

510(k) Summary

Submitter:
Pac-Dent International, Inc.
21038 Commerce Point Dr.
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Contact Person:
Wenying Zhu
Materials Engineer
909-839-0888 ext.111
Date Summary Prepared:
June 2014

Device Name

Trade Name: PacSeal™ Pit & Fissure Sealant
Common Name: Pit and Fissure Sealant
Device Classification: Class II
Classification Product Code: EBC
Classification Name: Pit and Fissure Sealant and Conditioner per 21 CFR 872.3765

Predicate Device

3M™ Clinpro™ Sealant (K992326)
Prevent Seal (K122521)

Description of Device

PacSeal™ Pit & Fissure Sealant is a fluoride releasing, light-cured acrylate resin designed to fill and seal the pits and fissures of teeth.

Indications for Use

Seal the pits and fissures in teeth

Summary of Biocompatibility Tests

The biocompatibility of PacSeal™ Pit & Fissure Sealant was found to be substantially equivalent to the predicate based on a risk assessment and the identification of legally marketed predicate devices for all ingredients in the chemical composition.

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Comparison of Technological Characteristics and Performance

Descriptive Information	**Subject Device** PacSeal™ Pit & Fissure Sealant	**Predicate Device** 3M™ Clinpro™ Sealant (K992326)	**Predicate Device** Prevent Seal (K122521)
Indication for Use	Seal the pits and fissures in teeth	Pit and fissure sealant	• To fill and seal pit and fissure depressions of teeth to prevent cavities • Covering layer or "initial layer" in the fabrication of esthetically demanding composite restorations • For repairs of composite restorations
Composition of Materials	TEGDMA BISGMA UDMA Glass particle filler (0.18μm -1.0μm) Photoinitiator	TEGDMA BISGMA Glass particle filler (0.1μm -5.0μm) Photoinitiator	UDMA TEGDMA HEMA Glass particle filler Photoinitiator
Physical Properties and FDA-Recognized Standards	Depth of Cure- ISO 6874-2005 : complies Compressive Strength: 181 MPa Diametral Tensile Strength: subject device is equivalent to the predicate device Film Thickness: subject device is equivalent to the predicate device Flexural Strength- ISO 4049-2009: complies Light Curing Time- ISO 6874-2005 : 30 sec Shear Bond Strength to Etched Enamel: subject device is equivalent to the predicate device	Depth of Cure- ISO 6874-2005 : 1.86 mm Compressive Strength: 210 MPa Diametral Tensile Strength: 37 MPa Film Thickness: 10μm Flexural Strength- ISO 4049-2009: 110 MPa Light Curing Time- ISO 6874-2005 : 30 sec Shear Bond Strength to Etched Enamel: 8.12 MPa	N/A
Delivery system	1.2 mL pre-filled syringe	1.2 mL pre-filled syringe 6 mL bottle	1.2 mL pre-filled syringe

Based on the above comparisons and performance test results, Pac-Dent concludes that the subject device is substantially equivalent in intended use, composition, delivery system and performance to the predicate device. Physical properties evaluated include depth of cure,

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compressive strength, diametral tensile strength, film thickness, flexural strength, light curing time and shear bond strength to etched enamel.

Substantial Equivalence

In summary, this submission demonstrates that PacSeal™ Pit & Fissure Sealant is substantially equivalent to the identified predicate products for its intended use.